K071169

Date: April 27, 2007

510(k) Summary

JUN 20 2007

3-1. 510(k) owner (submitter)

1) Name	KURARAY MEDICAL INC.
2) Address	1621 Sakazu, Kurashiki, Okayama 710-0801, Japan
3) Contact person	Michio Takigawa Quality Assurance Department
4) Contact person in U.S.	Koji Nishida KURARAY AMERICA INC. 600 Lexington Avenue, 26th Floor New York, NY 10022 Tel: (212)-986-2230 (Ext. 115) or (800)-879-1676 Fax: (212)-867-3543

3-2. Name of Device

1) Trade / Proprietary name	CLEARFIL MAJESTY Posterior PLT
2) Classification name	Tooth shade resin material (21 CFR section 872.3690. Product code: EBF)
3) Common name	Restorative composite resin
4) Device listing number	R001413

3-3. Predicate device

1) CLEARFIL MAJESTY Posterior	510(k) Number:	K063595
	Classification:	Tooth shade resin material
	Product Code:	EBF
	21 CFR Section:	872.3690
	Applicant:	KURARAY MEDICAL INC.
2) CLEARFIL AP-X PLT	510(k) Number:	K023002
	Classification:	Tooth shade resin material
	Product Code:	EBF
	21 CFR Section:	872.3690
	Applicant:	KURARAY MEDICAL INC.

3-4. Device Description

CLEARFIL MAJESTY Posterior PLT (PLT: Pre-loaded tip) is a light-cure, radiopaque restorative composite resin which provides accurate color matching, high polish ability and excellent physical properties, making it ideal for both anterior and posterior restorations. It is formulated with optimal viscosity assuring easy handling and placement. CLEARFIL MAJESTY Posterior PLT, with its special dispensing system, can be quickly and conveniently placed directly into the cavity.

CLEARFIL MAJESTY Posterior PLT, the applicant device, is substantially the same as CLEARFIL MAJESTY Posterior, the predicate device where the only difference is the container form; the applicant device comes in tips while the predicate device is filled in syringes. The tips used in the applicant device are the same as those used in CLEARFIL AP-X PLT, the predicate device, except for the color. Therefore, the applicant device is substantially equivalent to the predicate devices.

3-5. Substantial Equivalence Discussion

1) Intended uses

It is intended to be used for the indications listed in the left hand column of the below table that are equivalent to the predicate devices.

Table 3: Indications for Use and predicate devices

Indications for Use	Predicate devices
1) Direct restorations for anterior and posterior teeth (Class I – V cavities)	CLEARFIL MAJESTY Posterior, CLEARFIL AP-X PLT
2) Correction of tooth position and tooth shape (e.g. diastema closure, dwarfed tooth, etc.)	CLEARFIL MAJESTY Posterior
3) Intraoral repairs of fractured crowns/bridges	CLEARFIL MAJESTY Posterior

2) Chemical composition / Safety

All the chemical composition of CLEARFIL MAJESTY Posterior PLT, the applicant device, are exactly the same as those in CLEARFIL MAJESTY Posterior, the predicate device suggesting the safety of the applicant device is substantially equivalent to the predicat device.

3) Effectiveness / Performance

CLEARFIL MAJESTY Posterior PLT, the applicant device, is verified to comply with the requirements of the applicable FDA recognized consensus standard, ISO 4049: 2000 "Dentistry – Polymer-based filling, restorative and luting materials". As to compare with CLEARFIL MAJESTY Posterior, the predicate device, according to ISO 4049: 2000, both the applicant and the predicate devices comply with ISO 4049: 2000 indicating that the applicant device is as effective as and performs as well as the predicate device.

3-6. Biocompatibility

All the chemical compositions of CLEARFIL MAJESTY Posterior PLT, the applicant device, have been used in the predicate devices as shown in the table of "Section 7: Substantial Equivalence Discussion, Table: 7-2" where all the chemical compositions of the applicant device are listed in the left hand column and the predicate devices containing the composition are listed in the right hand. From that table, it can be said that the safety of the applicant device is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Kuraray Medical, Incorporated
C/O Mr. Koji Nishida
Kuraray America, Incorporated
600 Lexington Avenue, 26th Floor
New York, New York 10022

JUN 20 2007

Re: K071169
Trade/Device Name: CLEARFIL MAJESTY™ Posterior PLT
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth Shade Resin Material
Regulatory Class: II
Product Code: EBF
Dated: April 27, 2007
Received: May 03, 2007

Dear Mr. Nishida:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu S. Lin, PhD
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K071169

Device Name: CLEARFIL MAJESTY Posterior PLT

Indications for Use:

1) Direct restorations for anterior and posterior teeth (Class I – V cavities)
2) Correction of tooth position and tooth shape (e.g. diastema closure, dwarfed tooth, etc.)
3) Intraoral repairs of fractured crowns/bridges

Prescription Use X AND/OR Over-The-Counter Use N/A

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

R Betz DDS for Dr. Susan Runner

(Division Sign-Off)

Division of Anesthesiology, General Hospital, Infection Control, Dental Devices

510(k) Number K071169